

PATENT COOPERATION TREATY  
**PCT**  
 INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
 (PCT Article 36 and Rule 70)

REC'D 28 SEP 2004  
 WIPO PCT

Applicant's or agent's file reference 0351061001	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000705	International Filing Date (day/month/year) 5 June 2003	Priority Date (day/month/year) 6 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. 7 A61B 19/02 B65D 85/24		
Applicant LEITCH, Robert W.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I <input checked="" type="checkbox"/>	Basis of the report
II <input type="checkbox"/>	Priority
III <input checked="" type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV <input checked="" type="checkbox"/>	Lack of unity of invention
V <input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
VI <input type="checkbox"/>	Certain documents cited
VII <input type="checkbox"/>	Certain defects in the international application
VIII <input type="checkbox"/>	Certain observations on the international application

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Date of submission of the demand 6 January 2004	Date of completion of the report 21 September 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  MATTHEW FORWARD Telephone No. (02) 6283 2606

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/AU2003/000705

## I. Basis of the report

1. With regard to the elements of the international application:<sup>\*</sup>
  - the international application as originally filed.
  - the description, pages , as originally filed, pages , filed with the demand, pages , received on with the letter of
  - the claims, pages , as originally filed, pages , as amended (together with any statement) under Article 19, pages , filed with the demand, pages , received on with the letter of
  - the drawings, pages , as originally filed, pages , filed with the demand, pages , received on with the letter of
  - the sequence listing part of the description: pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language which is:
  - the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
  - the language of publication of the international application (under Rule 48.3(b)).
  - the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
  - contained in the international application in written form.
  - filed together with the international application in computer readable form.
  - furnished subsequently to this Authority in written form.
  - furnished subsequently to this Authority in computer readable form.
  - The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/fig.
5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).<sup>\*\*</sup>

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

the entire international application,  
 claims Nos: 21 to 24, 32 to 37

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

Claims 32 to 37 recite a method of utilising an instrument during surgery, including the step of retaining the instrument in a holder according to claims 1 to 31. Since only claims 1 to 20 directly define a holder, whilst claims 25 to 31 define a retainer suitable for use in a holder of claim 1 and claims 21 to 24 define a medical sharps removal device, claims 32 to 37 are appended in an unclear manner. As a consequence these claims are effectively unsearchable.

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claim Nos. 21 to 24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the standard.  
 the computer readable form has not been furnished or does not comply with the standard.

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## IV. Lack of unity of invention

## 1. In response to the invitation to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2.  This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

## 3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- complied with.
- not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Preliminary Examination Authority has found that there are different inventions as follows:

1. Claims 1 to 20 and 25 to 31 define a holder for surgical instruments characterised by there being a number of individual retaining portions mounted on a body to keep separate and retain the operating (distal) end of surgical instruments. It is considered that such a holder comprises a first "special technical feature".
2. Claims 21 to 24 are directed to a device for the removal of medical sharps with an aperture in a body to receive a sharp and a perpendicular extending lip to remove the sharp from the instrument to which it is attached. It is considered that such a sharp remover comprises a second "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori. No fees were paid by the applicant to search the second special technical feature.

## 4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
- the parts relating to claims Nos. 1 to 20, 25 to 31

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-20, 25-31	YES
	Claims	NO
Inventive step (IS)	Claims 4-7, 11-13, 17-20	YES
	Claims 1-3, 8-10, 14-16, 25-31	NO
Industrial applicability (IA)	Claims 1-20, 25-31	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 5181609 (SPEILMANN et al)
- D2 WO 2001/008583 (AESCULAP AG & CO. KG)
- D3 US 4693439 (HAHN)
- D4 WO 1996/039091 (ORTHOFIX S.R.L.)
- D5 GB 2316857 (KLEENEZE SEALTECH LIMITED)
- D6 DE 2834474 (AESCULAP WERKE AG)

The present application defines a "holder for surgical instruments" with a number of retainers mounted "on or in the body" of the holder and a separator located between adjacent retainers. The portion of the surgical instrument that engages with the patient is retained by and separated from an instrument held in an adjacent retainer. The retainer substantially encloses the engaging portions of the instruments. This combination of features is not suggested by any of documents D1 to D6 in isolation. Claims 1 to 20 and 25 to 31 are novel in view of document D1 to D6.

In document D1 either a magnetic surface or a block of foamed material retains medical sharps and instruments. D2 discloses a sterile container where internal walls (34) divide the container into a number of sections. Document D3 is directed to a knife block where in each knife is retained by the block and separated from adjacent knives in the block. The person skilled in the art would recognise that the instrument holder of D1 would be improved due to the entire instrument being retained and separated from adjacent instruments. Such a holder would substantially improve prevention of cross contamination. It is submitted that the medical instrument retaining device of document D1 when read in the light of either D2 or D3 provides a holder with the improvements as envisaged. Claims 1 and 10 lack an inventive step in view of this obvious combination of documents. The features of claims 2 and 3 are disclosed by D1. A tapered cavity (claim 8) is considered to be an obvious variation of the cavities of D3. The cavity shapes evident in D3 disclose the matter of claim 9. Stackable containers (re claim 14) are considered to be generic in the art, as is engagement between otherwise separate holders (re claim 15). The features of claim 16 are disclosed by D1 (see figure 3). A retainer that encloses a surgical instrument (claims 25 to 31) is considered to be disclosed by document D3, or by D1 in combination with D2. Claims 1 to 3, 8 to 10, 14 to 16 and 25 to 31 lack an inventive step in view of this obvious combination of documents.

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## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

## Continuation of Box V

Document D4 provides a holder for a number of surgical wires. Each wire is retained by and separated from an adjacent wire. D5 discloses a further knife block, wherein the handle portion protrudes from the block and a unit of flexible filaments retains the blade. The person skilled in the art would appreciate that a surgical instrument would more easily withdrawn from the block of D4 if more of the user operator end was protruding from the holder. Such a holder would be provided by document D4 when read in the light of D5. Claims 1 to 3 and 25 to 26 lack an inventive step in view of this obvious combination of documents. The matter of claims 8 to 10, 14 to 16 and 27 to 31 also lack an inventive step for similar reasons to discussed in connection with documents D1 to D3.